

## Stem Cell Agency Board Approves \$50 Million for CIRM 2.0, a "Radical Overhaul" of How it Drives Development of Stem Cell Treatments

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San Francisco, CA – "We want to dramatically change the way we drive the development of stem cell treatments, to make it easier for the best projects to get the support they need when they need it, and to get patients affected, directly involved in the battle. We believe CIRM 2.0 is a major step in that direction," says Dr. C. Randal Mills, the President and CEO of the California Institute for Regenerative Medicine (CIRM), the state's stem cell agency.

The CIRM Board unanimously approved a \$50M concept plan, referred to as CIRM 2.0, at its meeting in Berkeley today.

CIRM 2.0 is a streamlined process that will make it easier and faster to apply for funding from the stem cell agency, and is designed to attract high quality clinical stage projects that are ready to start within 45 days of being approved for funding.

"Our mission is to accelerate the development of stem cell treatments for patients with unmet medical needs," says Mills. "With many of these diseases, time lost waiting for a treatment means lives lost. We must continue to find new and innovative ways to speed up our process and make it easier to get promising therapies into clinical trials, and to give them all the support they need to be successful. That's why we undertook this radical overhaul of the way we do business."

In the past it could take up to two years for a researcher or company to move from applying for funding to getting the money as part of an approved contract. CIRM 2.0 simplifies and accelerates the process, cutting that two years down to just four months. And instead of just one single round of funding with an application deadline every, say, 12-to-18 months, CIRM 2.0 will have an open application process for clinical stage programs with deadlines every month. That means companies and researchers can apply when they are ready and won't have to try and rush an application in prematurely, for fear it could be another year or more before the chance comes around again.

"By making it easier to apply for funding we are not just looking for more applications, we're looking for more high quality applications," says Mills. "We want to attract the best ideas, the best science and the best scientists to California. That's why this applies to both corporate and academic researchers and even creates incentives for non-California organizations with promising technology to bring their programs into the state."

The program is not simply about providing funding; it's also about providing support. Each program will partner with a project-specific Clinical Advisory Panel (CAP) to help advise and guide it. These CAPs will include at least one of CIRM's internal science officers, outside experts and importantly, at least one patient representative to provide hands-on input from the unique perspective of someone living with the disease.

"These CAPs will be an integral part of the project team," says Mills. "Their role is to work with the researchers on a regular basis, to make recommendations and even suggest real-time course corrections when appropriate to keep the program on track. To this end, we think direct patient involvement will add tremendous value to the process."

CIRM 2.0 begins January 1<sup>st</sup>, 2015 and, to begin with, applies only to projects that are ready to start a clinical trial or are doing the work required by the Food and Drug Administration to gain approval for a clinical trial. However, the CIRM team plans on presenting proposals to the Board in 2015 to expand this program, with additional funding, to programs in the discovery and translational stages.

"When we hired Dr. Mills, we wanted him to stake stock of what has already been a highly successful program and to design ways to make it that much better," says Jonathan Thomas, Ph.D., J.D., Chair of the CIRM governing Board. "CIRM 2.0 does just that. Dr. Mills has created a dynamic new program and are very excited about further accelerating therapies to patients."

You can see a video of Dr. Mills talking about CIRM 2.0 on our website.

About CIRM: CIRM was established in November 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research.

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